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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------|---------------------|------------------|
| 10/822,254  | 04/09/2004  | Shahriar Shane Taremi | JB06017US01         | 1701             |
| 24265   | 7590        | 03/10/2005            | EXAMINER            |                  |
| SCHERING-PLOUGH CORPORATION<br>PATENT DEPARTMENT (K-6-1, 1990)<br>2000 GALLOPING HILL ROAD<br>KENILWORTH, NJ 07033-0530 |             |                       | ROOKE, AGNES BEATA  |                  |
|   |             |                       | ART UNIT            | PAPER NUMBER     |
|   |             |                       | 1653                |                  |

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/822,254

Applicant(s)

TAREMI ET AL.

Examiner

Agnes B Rooke

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 21 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 14-33 is/are pending in the application.
- 4a) Of the above claim(s) 6-13 and 34-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 16 and 21-32 is/are rejected.
- 7) ☒ Claim(s) 2-5, 14, 15, 17-20 and 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 1-5 and 14-33 are pending.

Claims 6-13 and 34-57 are cancelled.

Applicant's election without traverse of Group I, Claims 1-5 and 14-33, in the reply filed on December 21, 2004 is acknowledged.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The Applicant claims a polypeptide that is not isolated and purified.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 24, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is not clear what is the structure or function of the peptide *derived* from p53, SCH549128, Ac-6CWAC3cE, and Ac-6BrWAC3CE. For example, any derived peptide could be a sequence consisting of any few amino acids. Therefore, the written description requirement is not satisfied, since the Applicant did not adequately describe or disclose peptides that are derived from p53, SCH549128, Ac-6CWAC3cE, and Ac-6BrWAC3CE.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 21-23, and 25-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected because the name of Hdm2 must be spelled out.

Claim 25 is rejected because the names of SCH549128, Ac-6CWAC3cE, Ac-6BrWAC3CE must be spelled out.

Claim 26, 27, and 28 are rejected because they refer to Tables 3 or 4, and none of the values for the crystal 's structural coordinates are provided in the claims. Thus, one skilled in the art cannot provide adequate *prima facie* interpretation of the claims without referring to the specification.

Claims 21-23 are rejected because the claims use unascertained language "*of greater than*" and the value of RMSD is therefore indefinite.

Claims 29-31 are rejected because the claims use unascertained language "*less than about*" and the value of RMSD is therefore indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 16, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Burrell et al. (U.S. 5,420,263).

Claims 1, 16, and 32 refer to a polypeptide, or a crystal comprising the polypeptide of SEQ ID NO:4, "*wherein at least one of the seven variable positions of SEQ ID NO:4 has an amino acid residue that differs from that of the corresponding wild-type Hdm2 (17-125) amino acid sequence SEQ ID NO:2...*"

Burrell et al. teach human MDM2 gene that is genetically altered in human tumor cells, and where the human MDM2 protein binds to human p53. See Abstract.

In Claim 1, Column 23-26, Burrell et al. teach amino acid sequence (SEQ ID NO:2, that is 491 amino acids long) where the sequence has 7 mismatches where compared to the SEQ ID NO:2 (the wild type Hdm2 in Claims 1, 16, and 32).

Therefore, the reference meets the limitation of the claims, where at least one of the seven variable positions of SEQ ID NO:4 has an amino acid residue that differs from that of the corresponding wild-type Hdm2 as disclosed by Burrell et al.

**Conclusion**

No Claims are allowed.


SEQ ID NO: 6, SEQ ID NO:8, SEQ ID NO:10, and SEQ ID NO:12 are free of art.

Claims 2-5, 14, 15, 17-20, and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER